

REMARKS

Upon entry of this paper, claims 1 and 11 have been amended, no claims have been canceled, and no claims have been added as new claims. Thus, claims 1-20 are currently pending in the application, of which claims 1 and 11 are independent. No new matter has been added.

Interview Summary

Applicant thanks the Examiner for the telephone interview conducted with the Examiner on June 12, 2006 and the follow-up interview conducted with the Examiner and the Supervisory Patent Examiner on the same day. The topic of the follow-up interview focused on an issue newly introduced by the Supervisory Examiner (i.e., concerns with the term “plastically deformed”) and did not address the amendments proposed or discussed in the first interview with the Examiner. The first paragraph of the Interview Summary mailed June 19, 2006, summarizes the discussion. The claims have been amended herein to remove the language relating to plastic deformation, thus rendering further details of the discussion beyond that which has been characterized by the Examiner moot.

However, during the initial interview with just the Examiner and not the Supervisory Examiner, the pending claims and rejections were discussed. Despite the characterization in the Interview Summary mailed June 19th that “applicant’s representative did not provide the exact claim language that he intends to add”, Applicant’s representatives did, in fact, present exact and specific claim language regarding the proposed amendment to claim 1. The proposed claim language regarding the end of the shaft at which the thread begins was presented to the Examiner exactly as it is presented in this paper, “A furcated bone screw, comprising: a shaft having a first end and a second end; a screw thread extending from the second end and circumnavigating the shaft; and a plurality of elongate slots longitudinally formed in the shaft from the second end and creating a plurality of furcated branches ...” Furthermore, the Examiner stated that the proposed claim language appeared to address the Examiner’s concerns regarding patentability over the cited references, but that the Examiner would not make a definitive statement regarding whether the claim was allowable until after consulting with the Supervisory Examiner. Applicant respectfully requests that the Interview Summary be corrected to reflect that the Examiner agreed generally that the proposed language was acceptable to make the claim patentable over

the cited references, but that a final indication of patentability would be deferred until after consultation with the Examiner's Supervisor. Applicant further requests that claims 1 and 11 be allowed based on the amendments to claims 1 and 11 provided herein, which directly address all concerns raised by the Examiner and the Examiner's Supervisor.

Claimed Invention

The claimed invention is generally directed to a furcated orthopedic bone screw including a threaded portion that is cut or slotted into multiple radial segments. Each of the radial segments of the furcated bone screw bends in a radially outward direction to create a compressible screw tip of increasing diameter over the furcated portion of the screw. In use, the radial force of the threaded radial segments against the bone or prosthetic results in the furcated bone screw being better able to engage the bone or prosthetic to resist pull-out and compensate for stripped threads or soft bone.

Claim Rejections – 35 USC § 102

Claims 1-7 and 9-20 were rejected under 35 USC 102(e) as being anticipated by International PCT Application WO 02/34120 of Dudasik. Applicant respectfully traverses this rejection in view of the following remarks.

The Dudasik reference is generally directed to devices used in surgery for joining together bone and/or tissue. The devices typically are inserted into a hole created in the bone or tissue.

The Dudasik reference does not disclose each and every element of the claimed invention. Specifically, the Dudasik reference does not disclose, "wherein the plurality of branches bend radially outwardly from a first screw diameter to a relatively larger second circumferential diameter and are compressible to the first screw diameter without plastic deformation," as recited in amended independent claim 1. The Office Action cites Figs. 7A-7C and page 6, 2nd paragraph, to support the contention that the Dudasik reference discloses the aforementioned elements of claim 1. Fig. 7A shows an expansion sleeve 12 and an expander 34. There is no indication whatsoever that the sections of the expansion sleeve bend radially

outwardly in Fig. 7A. In Fig. 7C, the expander 34 has been forced into the sleeve which results in the sections expanding outward, however, the sections are not compressible to the first diameter in Fig. 7C because the expander inside the sleeve physically prevents the sections from compressing to the first diameter, with or without plastic deformation. Either the sections of the expansion sleeve do not bend radially outward, but may be compressed, as in Fig. 7A, or the expander has been inserted so that the sections bend radially outward, but they cannot be compressed to the first diameter as in Fig. 7C. The invention disclosed in the Dudasik reference does not permit the existence of both conditions at the same time. The Dudasik reference does not disclose each and every element of amended independent claim 1, thus, Applicant respectfully submits that amended independent claim 1 is in condition for allowance. Withdrawal and reconsideration of the rejection of claim 1 is requested.

Additionally, Applicant respectfully submits that the Dudasik reference does not disclose each and every element of amended independent claim 11. Specifically, the Dudasik reference does not disclose, "wherein the furcated means extend radially outwardly and are compressible," as recited in claim 11. As was discussed in the previous section, Fig. 7C shows a sleeve and expander combination with sections expanded outwardly, but the sleeve sections are not compressible as the expander physically blocks compression of the sleeve sections. The Dudasik reference discloses an expansion sleeve with sections that may be compressible, as in Fig. 7A, or that extend radially outward, as in Fig. 7C, but not both. Thus, the Dudasik reference does not disclose each and every element of amended independent claim 11, which is therefore allowable. Applicant respectfully requests reconsideration and withdrawal of the rejection of amended independent claim 11.

Claims 2-7 and 9-10 depend from amended independent claim 1, and are therefore allowable as depending from an allowable base claim, in addition to reciting their own patentable subject matter. Claims 12-20 depend from amended independent claim 11, and are therefore allowable as depending from an allowable base claim, in addition to reciting their own patentable subject matter. Thus, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 2-7, 9-10 and 12-20.

Claims 1-7 and 9-20 were rejected under 35 USC 102(e) as being anticipated by U.S. Patent No. 6,436,099 to Drewry et al. Applicant has amended claims 1 and 11 to clarify the configuration of the screw threads, and provides additional remarks below.

The Drewry reference is generally directed to an adjustable length tether for use in the spine and other parts of the body. The tether comprises an artificial strand with an eyelet formed in one end, the other end being looped through the eyelet. The other end is then secured with respect to the eyelet by a crimp.

The Drewry reference does not disclose each and every element of the claimed invention. Specifically, the Drewry reference does not disclose “a screw thread extending from the second end and circumnavigating the shaft; and a plurality of elongate slots longitudinally formed in the shaft from the second end and creating a plurality of furcated branches,” as recited in amended independent claim 1. The Office Action cites Fig. 9E to support the assertion that Drewry discloses the claimed invention. As can be seen in Fig. 9E, the screw thread extends from the opposite end of the mechanical crimp 50 from the end in which the slots are formed. Claim 1 recites a screw thread extending from the second end of the shaft and elongate slots longitudinally formed from the second end of the shaft. The Drewry reference discloses threads and slots at opposite ends of the crimp, while the claimed invention recites threads and slots extending from, and formed in, the same end of the bone screw. The present invention is a bone screw better able to resist pull-out. As the bone screw progresses past the initial hole and through the bone the branches expand. The expansion results in a screw in the bone with a larger diameter than the initial entry hole, which better resists pull-out from the bone and can compensate for stripped threads, (page 6, line 14 to page 7, line 5 and Fig. 5). The Drewry reference discloses a crimp whose branches are used to grip an artificial strand. Because the sections of the crimp are formed in the same end of the crimp as the thread, the initial entry hole of the crimp is larger than the diameter of a portion of the crimp that extends further into the bone. This results in a crimp whose branches can grip an artificial strand, but a crimp that is less able to resist pullout and cannot compensate for stripped threads. Drewry does not disclose each and every element of amended independent claim 1, which is therefore allowable. Reconsideration and withdrawal of the rejection of claim 1 is respectfully requested.

Additionally, the Drewry reference does not disclose each and every element of amended independent claim 11. Specifically, the Drewry reference does not disclose “a screw thread extending from the second end and circumnavigating the shaft; and a plurality of elongate slots longitudinally formed in the shaft from the second end and creating a furcated means,” as recited in amended independent claim 11. As was discussed in the previous paragraph, the Drewry reference discloses a mechanical crimp with a “screw” thread extending from an end of the crimp which is the opposite end from the end in which a slot is formed. In claim 11, the screw thread extends from the same end of the shaft as the end in which the longitudinal slots are formed. The Drewry reference does not teach each and every element of amended independent claim 11, which is therefore allowable. Reconsideration and withdrawal of the rejection of claim 11 is respectfully requested.

As was discussed previously, claims 2-7 and 9-10 depend from amended independent claim 1, and are therefore allowable as depending from an allowable base claim, in addition to reciting their own patentable subject matter. Claims 12-20 depend from amended independent claim 11, and are therefore allowable as depending from an allowable base claim, in addition to reciting their own patentable subject matter. Thus, Applicant again respectfully requests reconsideration and withdrawal of the rejection of claims 2-7, 9-10 and 12-20.

Claim Rejections – 35 USC § 103

Claim 8 was rejected under 35 USC 103(a) as being unpatentable over Dudasik. Applicant respectfully traverses the rejection with the following remarks.

The Dudasik reference does not teach or suggest each and every element of claim 8. The Office Action states that “Dudask disclose the claimed invention except for the plurality of furcated branches comprises three branches.” Applicant submits that the previous remarks establish that the Dudasik reference does not disclose each and every element of amended independent claim 1, from which claim 8 depends. Applicant further submits that the Dudasik reference does not teach or suggest “wherein the plurality of branches bend radially outwardly from a first screw diameter to a relatively larger second circumferential diameter and are compressible to the first screw diameter without plastic deformation,” as recited in amended

independent claim 1. The Dudasik reference does not teach or suggest each and every element of claim 1 or its dependent claim 8, thus claim 8 is allowable. Further, the subject matter of claim 8 is not obvious in light of the Dudasik reference. Reconsideration and withdrawal of the rejection of claim 8 is respectfully requested.

Claim 8 was rejected under 35 USC 103(a) as being unpatentable over Drewry et al. Applicant respectfully traverses the rejection with the following remarks.

The Drewry reference does not teach or suggest each and every element of claim 8. Applicant submits that the remarks above establish that the Drewry reference does not disclose each and every element of amended independent claim 1, from which claim 8 depends. Applicant further submits that the Drewry reference does not teach or suggest, “a screw thread extending from the second end and circumnavigating the shaft; and a plurality of elongate slots longitudinally formed in the shaft from the second end and creating a plurality of furcated branches,” as recited in amended independent claim 1, from which claim 8 depends.

Applicant further submits that the Drewry reference only discloses two branches for the crimp. There is no evidence that the optimum number of branches for a crimp, which is designed to hold an artificial fiber through compression radially inward, would be the same as the optimum number of branches for a bone screw designed to exert force radially outward against a bone. The choice of three branches is not obvious in light of the Drewry reference.

The Drewry reference does not disclose, teach or suggest all of the elements of claim 8. Further, claim 8 is not obvious in light of the Drewry reference, thus claim 8 is allowable. Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 8.

Regarding the Examiner's Response to Arguments

The Office Action indicates that Applicant's arguments with respect to the claims are moot in view of the new grounds of rejection. There is no maintenance of the prior grounds of rejection. Under MPEP §707.07(e) and *Paperless Accounting, Inc. v. Bay Area Rapid Transit System*, 804 F.2d 659, 231 USPQ 649, a requirement or rejection in a prior Office Action is withdrawn if the examiner does not repeat or refer to that requirement or rejection. Accordingly,

Applicant considers all rejections and objections to be either addressed or withdrawn upon filing of this Response. As such, all claims are now allowable, and action to that end is respectfully requested.

In addition, the Examiner has referred again to the Enyati reference on page 3, the last paragraph, of the most recent Office Action, and further provides language as to functional verses structural limitations. Since no actual rejection has been stated or maintained with respect to the Enyati reference, it appears that this paragraph is merely provided as commentary. To the extent that any form of rejection is intended, Applicant respectfully traverses in view of the remarks provided herein as to the patentability of the pending claims based on their structural differences from devices found in the cited references.

CONCLUSION

In view of the foregoing, it is respectfully submitted that this application is now in condition for allowance. Applicant courteously solicits allowance of the claims in the form of a Notice of Allowance. Each of the Applicant's claims contains characteristics that are neither disclosed nor suggested by the cited documents. For the reasons detailed herein, Applicant respectfully requests that all rejections be reconsidered and withdrawn. This application is in condition for allowance, and notice of the same is earnestly solicited. Should the examiner have any questions, comments, or suggestions in furtherance of the prosecution of this application, the Examiner is invited to contact Applicant's representative by telephone at the number indicated below.

Please charge any shortage or credit any overpayment of fees to our Deposit Account No. 12-0080. In the event that a petition for an extension of time is required to be submitted herewith, and the requisite petition does not accompany this response, the undersigned hereby petitions under 37 C.F.R. §1.136(a) for an extension of time for as many months as are required to render this submission timely.

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Respectfully submitted,

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